REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

Claim 6 has been amended to add terminology on a coating of antigens, which is supported in the specification at page 18.

In the Office Action of August 11, 2008, the Examiner took the following actions to which Applicant herein makes response: (1) stated that the listing of references in the specification was not a proper Information Disclosure Statement and had not been considered; (2) objected to claim 6 for the spelling of "simultaneous"; (3) rejected claims 6 and 7 under Section 112, second paragraph regarding the "means" phrases; (4) rejected claims 6 and 7 under Section 103(a) as being unpatentable over Hayette et al., Wakshull et al. and Kanbe et al.; and (5) rejected claims 6 and 7 under Section 103(a) as being unpatentable over Sendid et al., Wakshull et al., and Kanbe et al. These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 6-7 now pending in the application.

(1) Listing of references in the specification

Applicant respectfully submits that the listing in the specification, with the exception of the references on the attached late-submitted Information Disclosure Statement, was simply a list of references discussed in the application but not intended to be submitted in an Information Disclosure Statement. A separately filed Petition and fee are attached for the late submission of this Information Disclosure Statement for five of those references that were unintentionally not previously included in an Information Disclosure Statement.

(2) Objection to claim 6 for the spelling of "simultaneous"

Claim 6 has been amended to correct the spelling, and therefore this objection has been overcome.

(3) Rejection of claims 6 and 7 under Section 112, second paragraph regarding the "means" phrases

Applicant respectfully submits that this rejection is unclear. Applicant has reviewed the language of claim 6 and language of the cited paragraph of Section 112, which follows:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Applicant respectfully submits that Applicant believes that the language of claim 6 as filed meets the requirements of paragraph 6 of Section 112 and clearly and directly expresses "a means or step for performing a specified structure" as required, and in fact is in that exact format. Specifically the claim as filed expresses a "means for drawing a sample" and a "means for an assay for the detection of a combination..."; however, in an attempt to try to respond to the rejection in which the Examiner talks about "word(s) *preceding* 'means'", Applicant has amended these two phrases to add words preceding "means" as follows:
"a sampling means for drawing a sample from a patient;
an assay means for an assay for the detection of a combination...". Applicant has also added terminology regarding antigen coating.

If this is not what the Examiner was asking for in making this rejection, Applicant respectfully requests further clarification of this rejection.

(4) Rejection of claims 6 and 7 under Section 103(a) as being unpatentable over Hayette et al., Wakshull et al. and Kanbe et al.

Hayette et al. teaches the study of human antibodies reacting with *Candida* O-linked oligomannosides using an ELISA assay. Hayette et al studied and characterized new epitopes of individual oligomannosides obtained by depolymerization of the PPM molecule to find new antigens for i.e the development of antibodies against them. He studied the molecular

basis of human antibody response against cell wall mannan under candidiasis and mentioned the importance of a specific method for IgM antibody against -PPM as it is known to be the predominant isotype against polysaccharides. However in the invention herein, human serum IgG antibodies to solubilized PPM or as a native cell wall constituent showed the strongest difference regarding patients with candidemia and healthy controls. No significantly increased IgM antibody levels were observed for any of the antigens suggesting that the *C. albicans* infection was not a first time challenge. Most probably the patients had been exposed to *Candida* earlier in life. Since the results of the inventors herein show no discriminatory effect of IgM antibodies, improved discrimination would be expected by using IgG antibody specific methods.

Wakshull et al. teaches methods of isolating β(1-3)-glucan or organisms containing it, and not methods according to the invention herein.

Kanbe et al. teaches isolating and use of phosphomannoproteins and portions thereof using a dot blot test to detect IgE antibodies specific to the cell wall phosphomannoproteins of *C. albicans*, and worked with allergenic patients who are positive for IgE antibodies to *C. albicans*. The group of patient, the aim of his study, the analysis method used, the antigen used, the subtype of the *C. albicans* antibody to be detected, everything is different from the invention herein.

The invention as claimed herein differs from the cited prior art by the specification of the antibody type (subclass and subtype) and the fact that a simultaneous presence of all three components of the invention indicates Candidiasis or invasive Candidiasis in the patient. The technical effect associated with that change is higher specificity and sensitivity of said diagnosis method. The problem to be solved by the present application might be regarded as a provision of diagnosis test for *Candida* infection with improved predictive value. Although a combination of the cited prior art could disclose all three entities being a subject for a diagnostic test for Candidiasis, it does not contain any hint that said entities could be tested in combination for improved diagnosis. Neither does it disclose specific antibody subclasses, which, according to the present application, have a discriminatory advantage over other

immunoglobulin subclasses. Therefore a skilled person would not regard as an obvious design to combine all three entities in one diagnosis test and look only to the specific antibody subclasses to arrive at a claimed effect

Applicant therefore submits that claim 6, and claim 7 which depends therefrom, are patentable over the cited references under Section 103(a).

(5) Rejection of claims 6 and 7 under Section 103(a) as being unpatentable over Sendid et al., Wakshull et al. and Kanbe et al.

Applicant incorporates herein the above remarks with respect to Wakshull et al. and Kanbe et al.

Sendid et al. uses a method that combines detection of both mannan and mannan antibodies, with a double-sandwich enzyme immunoassay. A problem with detection of *Candida* antibodies is that healthy patients usually are naturally immunized with *Candida* in their normal flora, and therefore already have antibodies to *Candida* antigens. In contrast, Applicant's invention utilizes particular antibody subclasses as set forth in claim 6. Wakshull et al discloses the diagnosis of Candidiasis by detection of B-glucans and Kanbe et al, discloses the use of a dot blot test to detect IgE antibodies specific to the cell wall phosphomannoproteins of *C. albicans*.

Nothing in Sendid et al. teaches or suggests testing for the particular antibodies plus glucan as set forth in claim 6 as amended. Even if Sendid et al. is combined with Waskshull et al. and Kanbe et al. there still is no teaching that means for performing these three assays be combined in a kit. As discussed above, nothing in any of these references, nor the combination thereof, teaches or suggests a diagnostic kit for the diagnosis of candidiasis or invasive candidiasis comprising a sampling means for drawing a sample from a patient; and an assay means as set forth in claim 6 as amended. In particular, none of these references nor the combination thereof teach or suggest an assay for the detection of a *combination of* an IgG2 antibody to a phosphopeptidomannan (PPM) fraction of the cell wall of *C albicans*, and an IgG1 antibody to a *C albicans* cell wall antigen, and glucan, utilizing a coating of *Candida*

antigens to test for the IgG2 antibody and the IgG1 antibody, wherein said sample is analyzed for the presence of the simultaneous presence of an IgG2 antibody to a phosphopeptidomannan (PPM) fraction of the cell wall of *C albicans*, and an IgG1 antibody to a *C albicans* cell wall antigen, and glucan (emphasis added).

Applicant therefore submits that claim 6, and claim 7 which depends therefrom, are patentable over the cited references under Section 103(a).

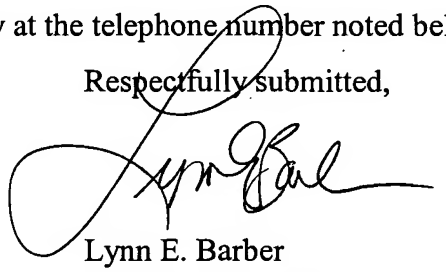
Conclusion

For all the foregoing reasons, claims 6-7 are submitted to be fully patentably distinguished over the cited references and in allowable condition. Favorable consideration is therefore requested.

This response is being filed on November 12, 2008, as November 11, 2008 was a United States federal/Patent Office holiday. Therefore no late fee is due for the filing of this amendment. It is believe that no other fee is required for the presentation of this amendment. Any amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,



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Enclosures:

1) Information Disclosure Statement, petition and fee